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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved abbreviated new animal drug applications (ANADAs) from Blue Ridge Pharmaceuticals, Inc., to Virbac AH, Inc.

DATES: This rule is effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 200-270 for IVERHART (ivermectin) Tablets, NADA 200-281 for WORMEXX (pyrantel pamoate) Chewable Tablets, and NADA 200-302 for IVERHART Plus (ivermectin/pyrantel pamoate) Flavored Chewable Tablets to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137. Accordingly, the agency is amending the regulations in 21 CFR 520.1193, 520.1196, and 520.2041 to reflect the transfer of ownership.

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NADA 200-270

NFR 2

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1193 [Amended]

2. Section 520.1193 Ivermectin tablets and chewables is amended in paragraph (b)(2) by removing "065274" and by adding in its place "051311".

§ 520.1196 [Amended]

3. Section 520.1196 Ivermectin and pyrantel pamoate chewable tablet is amended in the section heading by removing "tablet" and by adding in its place "tablets"; and in paragraph (b) by removing "065274" and by adding in its place "051311".

§ 520.2041 [Amended]

4. Section 520.2041 Pyrantel pamoate chewable tablets is amended in paragraph (b) by removing "065274" and by adding in its place "051311".

Dated: ~~April 3, 2002~~
April 3, 2002.

Andrew J. Beaulieu,
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicne.

[FR Doc. 02-????? Filed ??-??-02; 8:45am]

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